Table 2-1. Recommended Strategy for State Fish and Shellfish Contaminant Monitoring Programs

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Objective (see Section 2)	Identify frequently fished sites where commonly consumed fish and shellfish target species are contaminated and may pose potential human health risk.	Assess and verify magnitude of tissue contamination at screening site for commonly consumed target species.	Assess geographic extent of contamination in selected size classes of commonly consumed target species.
Target species and size classes (see Sections 3 and 6)	Select target species from commonly consumed species using the following additional criteria: known to bioaccumulate high concentrations of contaminants and distributed over a wide geographic area. Recommended types of target species: Inland fresh waters: 1 predator — 1 bottom-feeder Great Lakes: 1 bottom-feeder, 1 predator Estuarine/ marine: 1 shellfish and 1 fish species, or 2 fish species (one species should be bottom-feeder).	Resample target species at sites where they were found to be contaminated in screening study.	Resample at additional sites in the waterbody three size classes of the target species found to be contaminated in Phase I study.

See notes at end of table.

(continued)

Table 2-1 (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Target species and size classes (continued)	OPTIONAL: If resources are limited and a State cannot conduct Tier 2 intensive studies, the State may find it more cost-effective to collect additional samples during the Tier 1 screening study. States may collect (1) one composite sample of each of three size classes for each target species, (2) replicate composite samples for each target species, or (3) replicate composite samples of each of three size classes for each target species.	OPTIONAL: If resources are limited and a State cannot conduct Tier 2, Phase II, intensive studies, the State may find it more cost-effective to collect additional samples during the Tier 2, Phase I, intensive study. States may collect replicate composite samples of three size classes of the target species found to be contaminated to assess size-specific contaminant concentrations. Other commonly consumed target species may also be sampled if resources allow.	OPTIONAL: If resources allow, select additional commonly consumed target species using same criteria as in Phase I study.
Target analytes (see Section 4)	Consider all target analytes listed in Table 4-1 for analysis as resources allow. Include additional site-specific target analytes as appropriate based on historic data.	Analyze only for those target analytes from Tier 1 screening study that exceeded SVs.	Analyze only for those target analytes from Tier 2, Phase I, study that exceeded SVs.

See notes at end of table.

(continued)

Table 2-1 (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Screening values (see Section 5)	Calculate SVs using oral RfDs for noncarcinogens and using oral slope factors and an appropriate risk level (10^{-4} to 10^{-7}) for carcinogens, for adults consuming 6.5 g/d to 140 g/d or more of fish and shellfish (based on site-specific dietary data). **Note:** In this guidance document, EPA's Office of Water used a 6.5-g/d consumption rate, 70-kg adult body weight, and, for carcinogens, used a 10^{-5} risk level, 70-year exposure, and assumed no loss of contaminants during preparation or cooking. States may use other SVs for site-specific exposure scenarios by adjusting values for consumption rate, body weight, risk level, exposure period, and contaminant loss during preparation or cooking.	Use same SVs as in screening study.	Use same SVs as in screening study.
Sampling sites (see Section 6)	Sample target species at sites in each harvest area that have a high probability of contamination and at presumed clean sites as resources allow.	Sample target species at each site identified in the screening study where fish/shellfish tissue concentrations exceed SVs to assess the magnitude of contamination.	Sample at additional sites in the harvest area three size classes of the target species found to be contaminated in Phase I study to assess the geographic extent of the contamination in the waterbody.

See notes at end of table.

(continued)

Table 2-1 (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Sampling times (see Section 6)	Sample during legal harvest season when target species are most available to consumers. Ideally, sampling time should not include the spawning period for target species unless the target species can be legally harvested during this period.	Same as screening study.	Same as screening study.
Sample type (see Sections 6 and 7)	Collect composite fillet samples (skin on, belly flap included) for each target fish species and composite samples of edible portions of target shellfish species. The exceptions to the "skin on, belly flap included" recommendation is to use skin-off fillets for catfish and other scaleless species.	Same as screening study.	Same as screening study but collect composite samples for three size classes of each target species.
	OPTIONAL: States may use individual fish samples, whole fish, or other sample types, if necessary, to improve exposure estimates of local fish-, shellfish-, or turtle-consuming populations.	Same as screening study.	Same as screening study.
Sample replicates (see Section 6)	Collect one composite sample for each target species. **Collection of replicate composite samples is encouraged but is optional**. If resources allow, collect a minimum of one replicate composite sample for each target species at 10% of the screening sites for QC.	Collect replicate composites for each target species at each Phase I site.	Collect replicate composites of three size classes for each target species at each Phase II site.

See notes at end of table.

(continued)

Table 2-1 (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Sample analysis (see Section 8)	Use standardized and quantitative analytical methods with limits of detection adequate to allow reliable quantitation of selected target analytes at or below SVs.	Use same analytical methods as in screening study.	Use same analytical methods as in screening study.
Data analysis and reporting (see Sections 6, 7, 8, and 9)	For each target species, compare target analyte concentrations of composite sample with SVs to determine which sites require Tier 2, Phase I, intensive study.	For each target species, compare target analyte arithmetic mean concentrations of replicate composite samples with SVs to determine which sites require Phase II intensive study. If resources are insufficient to conduct Phase II intensive study, conduct a risk assessment and assess the need for issuing a preliminary fish or shellfish consumption advisory.	For each of three size classes within each target species, compare target analyte arithmetic mean concentrations of replicate composite samples at each Phase II site with SVs to determine geographic extent of fish or shellfish contamination. Assess the need for issuing a final fish or shellfish consumption advisory.
	The following information should be reported for each target species at each site:	The following information should be reported for each target species at each site:	The following information should be reported for each of three size classes within each target species at each site:
	• Site location (e.g., sample site name, waterbody name, type of waterbody, and latitude/longitude)	• Same as screening study.	• Same as screening study.
	• Scientific and common name of target species	• Same as screening study	• Same as screening study

See notes at end of table.

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Table 2-1 (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Data analysis and reporting (continued)	• Sampling date and time	• Same as screening study	• Same as screening study
	• Sampling gear type used	• Same as screening study	• Same as screening study
	• Sampling depth	• Sampling depth	• Sampling depth
	• Number of QC replicates (optional)	• Number of replicates	• Same as Phase I study
	• Number of individual organisms used in the composite sample and in the QC replicate composite sample if applicable	• Number of individual organisms used in each replicate composite sample	• Same as Phase I study
	• Predominant characteristics of specimens used in the composite sample and in the QC replicate if applicable (e.g., life stage, age, sex, total length or body size) and description of fish fillet or edible parts of shellfish (tissue type) used	• Predominant characteristics of specimens used in each replicate composite sample (e.g., life stage, age, sex, total length or body size) and description of fish fillet or edible parts of shellfish (tissue type) used	• Same as Phase I study
	• Analytical methods used (including a method for lipid analysis) and method detection and quantitation limits for each target analyte.	• Same as screening study	• Same as screening study
	• Sample cleanup procedures	• Same as screening study.	• Same as screening study.
	• Data qualifiers	• Same as screening study.	• Same as screening study.
	• Percent lipid in each composite sample.	• Same as screening study.	• Same as screening study.

See notes at end of table.

(continued)

Table 2-1 (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Data analysis and reporting (continued)	• For each target analyte:	• For each target analyte:	• For each target analyte:
	- Total wet weight of composite sample (g) used in analysis	- Total wet weight of each replicate composite sample (g) used in analysis	- Same as Phase I study
	- Measured concentration (wet weight) in composite sample including units of measurement for target analyte	- Measured concentration (wet weight) in each replicate composite sample and units of measurement for target analyte	- Same as Phase I study
	- Measured concentration (wet weight) in the QC replicate, if applicable.	- Range of concentrations (wet weight) for each set of replicate composite samples	- Same as Phase I study
		- Mean (arithmetic) concentration (wet weight) for each set of replicate composite samples	- Same as Phase I study
		- Standard deviation of mean concentration (wet weight)	- Same as Phase I study
	- Evaluation of laboratory performance (i.e., description of all QA and QC samples associated with the sample(s) and results of all QA and QC analyses)	- Same as screening study	- Same as screening study
	- Comparison of measured concentration of composite sample with SV and clear indication of whether SV was exceeded	- Comparison of target analyte arithmetic mean concentration of replicate composite samples with SV using hypothesis testing and clear indication of whether the SV was exceeded	- Same as Phase I study

QA = Quality assurance.
QC = Quality control.
RfDs = Reference doses.
SVs = Screening values.